

## **REMARKS**

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the amendments and remarks herein.

### **I. STATUS OF THE CLAIMS AND FORMAL MATTERS**

Claims 40-51 are now pending. Claims 40-51 have been amended, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

Support for the amendment of claims 40-42, 44-46 and 48-50, which directs the claims to methods consisting of administering a pharmaceutical composition to a patient in need thereof, wherein the pharmaceutical composition consists of a single inhibitor of the retinoic acid biosynthetic pathway, which is carbenoxolone, and one or more pharmaceutically acceptable carriers, diluents or excipients, can be found, for example, on page 70, line 6 – page 75, line 11.

Claims 43, 47 and 51 have been amended herein to correct a misspelling. Claims 40, 44 and 48 have been amended herein to add the recitation “cancers and pre-malignant” conditions to the list of diseases to be treated. Applicants respectfully submit that such a recitation is within the elected subject matter because cancers and pre-malignant conditions are hyperproliferative diseases (as elected) that can be treated by inhibition of the retinoic acid biosynthesis pathway by carbenoxolone. Thus, Applicants respectfully submit that continued examination of the pending claims should include the newly added recitation.

No new matter is added.

It is submitted that these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments to the claims and the remarks herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but rather the amendments and remarks are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

### **II. THE OBJECTION TO THE CLAIMS IS OVERCOME**

Claims 43 and 51 were objected to as being dependent upon a rejected base claim. Applicants respectfully submit that the remarks and enclosures herein have overcome the rejections of claim 40, upon which claim 43 depends, and those of claim 48, upon which claim

51 depends. Accordingly, it is respectfully believed that claims 43 and 51 are now allowable, and reconsideration and withdrawal of the objection to the claims is respectfully requested.

Claim 48 was objected to as containing a misspelling. Applicants respectfully submit that the amendment herewith has corrected this misspelling, such that the objection is now moot. Accordingly, reconsideration and withdrawal of the objection to the claim is respectfully requested.

### **III. THE INDEFINITENESS REJECTION IS OVERCOME**

Claims 44-47 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. The rejection is respectfully traversed.

The Office Action was not persuaded by Applicants' previous remarks and maintained that the claims do not clearly define whether carbenoxolone is topically administered to skin affected by, and thus in need of treatment, of a hyperproliferative disease. According to the Office Action, the claims provide for circumstances in which any portion of the skin is treated. Applicants respectfully disagree.

Initially, Applicants draw attention to instant claims 44-47, which are directed to a method of treating a hyperproliferative disease by topically administering to skin **that is to be treated** a pharmaceutical composition consisting of a single inhibitor of the retinoic acid biosynthetic pathway, which is carbenoxolone, and one or more pharmaceutically acceptable carriers, diluent or excipients. Therefore, according to the claims, the pharmaceutical composition is administered to skin "that is to be treated." With this mind, Applicants assert that one skilled in the art would clearly recognize to what skin the claimed methods is to be applied.

As the Office Action conceded, the claims are to be given the broadest reasonable interpretation consistent with MPEP §2111. See Office Action, page 3. MPEP §2111 indicates that claims are to be given their broadest reasonable interpretation **consistent with the specification**. Moreover, the scope of claims should be interpreted based on the claim language as well as the broadest reasonable construction of the claims "in light of the specification as it would be interpreted by one of ordinary skill in the art." *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364[, 70 USPQ2d 1827] (Fed. Cir. 2004).

Applying the guidance by the MPEP to the instant facts, the claims recite that the composition is applied to an “area to be treated.” The specification clearly indicates that the area to be treated refers to portions of the skin which is affected or portions in which treatment is desired. In addition, one skilled in the art would recognize that a treatment for a hyperproliferative skin disease should be applied to parts of the skin which need such treatment. This excludes area of the skin which are unaffected by the hyperproliferative disease and display no predisposition to the disease.

Accordingly, Applicants respectfully submit that the recitation of “administration to skin that is to be treated” is sufficiently clear to the skilled artisan in view of the specification and the teachings of the art as a whole. Consequently, reconsideration and withdrawal of the indefiniteness rejection is respectfully requested.

#### IV. THE ART REJECTIONS ARE OVERCOME

Claims 40-42, 44-46, and 48-50 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Burchardt *et al.* (WO 97/15298).

The Office Action maintains that the claims do not preclude the presence of additional components or steps, even though the claims recited a method consisting essentially of administering an inhibitor to a patient, wherein the inhibitor is carbenoxolone. The Office Action further alleges that the use of the transition phrase “consisting essentially of” in the claims does not exclude the combination of carbenoxolone with an LTD4 antagonist. The Office Action further contended that specification describes carbenoxolone in combination with other active ingredients.

In response, Applicants again note the instant claims, wherein the claimed methods are directed to treating a hyperproliferative disease of the skin consisting of administering a pharmaceutical composition consisting of a single inhibitor of the retinoic acid biosynthetic pathway which is carbenoxolone, and one or more pharmaceutically acceptable carriers, diluents or excipients. Clearly, the claimed invention relates to the use of carbenoxolone as the active ingredient and excludes the use of any other inhibitors.

Notably, Burkhardt *et al.* does not teach or suggest each and every element of the claimed invention. Burkhardt *et al.* relates to the use of carbenoxolone sodium and an LTD4 receptor antagonist, and not carbenoxolone alone as disclosed in the instant claims. In fact, the inclusion

of the LTD4 receptor antagonist in Burkhardt *et al.* may be viewed as teaching away from the instant invention, since the instant invention consists of only carbenoxolone and carriers, diluents or excipients. Therefore, the present invention is patentable and non-obvious over Burkhardt *et al.*

Reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) are thereby respectfully requested.

### **REQUEST FOR INTERVIEW**

If any issue remains as an impediment to allowance, an interview with the Examiner is respectfully requested, prior to issuance of any paper other than a Notice of Allowance; and, the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

### **CONCLUSION**

For the reasons stated above, applicant respectfully requests a favorable reconsideration of the application, reconsideration and withdrawal of the rejections of and objections to the instant application, and prompt issuance of a Notice of Allowance.

Respectfully submitted,  
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